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*"Your Regulatory Compliance Expert"*

April 7, 2016

Mr. Raju Patel
Senior Manager, Dangerous Goods and Environmental Programs
ABBOTT VASCULAR
26531 Ynez Road
Temecula, California 92591

Subject: **RESULTS OF ANNUAL ETHYLENE OXIDE SOURCE TESTING AND LEAK TESTING PERFORMED AT ABBOTT VASCULAR IN TEMECULA, CALIFORNIA**

Dear Mr. Patel:

Please find attached a presentation of the results of the ethylene oxide source testing and leak testing performed at your facility by ECSi, on Thursday, April 7, 2016. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate your EtO sterilization and emission-control system (SCAQMD Permit Numbers F83294, F71623, F83295, and F83299) in compliance with SCAQMD Rule 1405. I will follow up with you in approximately five months to let you know when your next semi-annual leak test is due, and in approximately eleven months to let you know when your next annual source test/leak test is due.

The annual ethylene oxide emissions reported in Table 3 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

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# TABLE 1
## ETHYLENE OXIDE CONTROL EFFICIENCY
## OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE - ABATOR #2 (F83299)
## OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
## IN TEMECULA, CALIFORNIA
## ON APRIL 7, 2016

| CYCLE PHASE | INJECTION TIME | INLET ETO CONC. (PPM)(1) | OUTLET ETO CONC. (PPM)(2) | ETO CONTROL EFFICIENCY |
|---|---|---|---|---|
| Exhaust(3) | 1247 | 2510 | 0.01 | 99.9996 |
| Exhaust | 1249 | 7480 | 2.30 | 99.9693 |
| Exhaust | 1251 | 5550 | 0.01 | 99.9998 |
| Exhaust | 1253 | 4590 | 0.01 | 99.9998 |
| Exhaust | 1255 | 284 | 0.01 | 99.9965 |
| Exhaust | 1257 | 8.95 | 0.01 | 99.8883 |
| Exhaust | 1259 | 3980 | 0.01 | 99.9997 |
| Exhaust | 1301 | 3260 | 0.01 | 99.9997 |
| Exhaust | 1303 | 2370 | 0.01 | 99.9996 |
| Exhaust | 1305 | 1910 | 0.01 | 99.9995 |
| Exhaust | 1307 | 1240 | 0.01 | 99.9992 |
| Exhaust | 1309 | 765 | 0.01 | 99.9987 |
| Exhaust | 1311 | 99.0 | 0.01 | 99.9899 |
| Exhaust | 1313 | 9.18 | 0.01 | 99.8911 |
| Exhaust | 1315 | 5.76 | 0.01 | 99.8264 |
| **TIME-WEIGHTED AVERAGE:** | | **2271** | **0.1627** | **99.9705** |
| Aeration | 1317 | 812 | 0.01 | 99.9988 |
| Aeration | 1319 | 867 | 0.01 | 99.9988 |
| Aeration | 1321 | 123 | 0.01 | 99.9919 |
| **TIME-WEIGHTED AVERAGE:** | | **600.7** | **0.0100** | **99.9965** |
| | | | **TIME-WEIGHTED AVERAGE CONTROL EFFICIENCY:** | **99.9748** |
| | | | **SCAQMD REQUIRED CONTROL EFFICIENCY:** | **99.0** |

Notes:
(1) - PPM = parts per million by volume
(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
(3) - The exhaust phase started at 12:45, ended at 13:16.
(4) - The aeration phase started at 13:16, the first chamber evacuation was tested.

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# TABLE 2
## ETHYLENE OXIDE CONTROL EFFICIENCY
## OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE - ABATOR #1 (F71623)
## OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
## IN TEMECULA, CALIFORNIA
## ON APRIL 7, 2016

| CYCLE PHASE | INJECTION TIME | INLET ETO CONC. (PPM)(1) | OUTLET ETO CONC. (PPM)(2) | ETO CONTROL EFFICIENCY |
|---|---|---|---|---|
| Exhaust(3) | 1329 | 131 | 0.01 | 99.9924 |
| Exhaust | 1331 | 9910 | 0.01 | 99.9999 |
| Exhaust | 1333 | 8410 | 0.01 | 99.9999 |
| Exhaust | 1335 | 5640 | 0.01 | 99.9998 |
| Exhaust | 1337 | 2100 | 0.01 | 99.9995 |
| Exhaust | 1339 | 64.3 | 0.01 | 99.9844 |
| Exhaust | 1341 | 3670 | 0.01 | 99.9997 |
| Exhaust | 1343 | 3210 | 0.01 | 99.9997 |
| Exhaust | 1345 | 2680 | 0.01 | 99.9996 |
| Exhaust | 1347 | 2350 | 0.01 | 99.9996 |
| Exhaust | 1349 | 10.2 | 0.01 | 99.9020 |
| Exhaust | 1351 | 1980 | 0.01 | 99.9995 |
| Exhaust | 1353 | 1420 | 0.01 | 99.9993 |
| Exhaust | 1355 | 651 | 0.01 | 99.9985 |
| Exhaust | 1357 | 105 | 0.01 | 99.9905 |
| **TIME-WEIGHTED AVERAGE:** | | **2822** | **0.0100** | **99.9909** |
| Aeration | 1359 | 892 | 0.01 | 99.9989 |
| Aeration | 1401 | 403 | 0.01 | 99.9975 |
| Aeration | 1403 | 87.1 | 0.01 | 99.9885 |
| **TIME-WEIGHTED AVERAGE:** | | **460.7** | **0.0100** | **99.9950** |
| | | | **TIME-WEIGHTED AVERAGE CONTROL EFFICIENCY:** | **99.9916** |
| | | | **SCAQMD REQUIRED CONTROL EFFICIENCY:** | **99.0** |

Notes:
(1) - PPM = parts per million by volume
(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
(3) - The exhaust phase started at 13:27, ended at 13:58.
(4) - The aeration phase started at 13:58, the first chamber evacuation was tested.

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**TABLE 3**
**ETHYLENE OXIDE MASS EMISSIONS**
**FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM**
**OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS**
**IN TEMECULA, CALIFORNIA**
**ON APRIL 7, 2016**

| CYCLE PHASE | STACK FLOW(1) | OUTLET ETO MASS FLOW(2) | MINUTES/ CYCLE | CYCLES/ YEAR | ANNUAL ETO MASS EMISSIONS(3) |
|---|---|---|---|---|---|
| **Abator #1 (F71623) - Sterilizer #1 (F83294)** | | | | | |
| Exhaust | 49.5 DSCFM | 0.00000006 lbs/min | 31 | 104 | 0.0003 lbs/year |
| Aeration | 49.5 DSCFM | 0.00000006 lbs/min | 6 | 104 | 0.0001 lbs/year |
| **Abator #2 (F83299) - Sterilizer #2 (F83295)** | | | | | |
| Exhaust | 48.0 DSCFM | 0.00000089 lbs/min | 31 | 104 | 0.0029 lbs/year |
| Aeration | 48.0 DSCFM | 0.00000005 lbs/min | 6 | 104 | 0.0001 lbs/year |
| | | **TOTAL ANNUAL ETO MASS EMISSIONS:** | | | **0.0034 lbs/year** |

Notes:
(1) - DSCFM = Dry Standard Cubic Feet per Minute
(2) - lbs/min = pounds per minute
(3) - lbs/year = pounds per year

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**TABLE 4**
**ETHYLENE OXIDE LEAK TESTING**
**OF A GAS STERILIZATION SYSTEM**
**OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS**
**IN TEMECULA, CALIFORNIA**
**ON APRIL 7, 2016**

| COMPONENT GROUP TESTED | LEAKING COMPONENTS FOUND | CONCENTRATION |
|---|---|---|
| **Sterilizer #1 - Model 8XL (SCAQMD Permit F83294)** | | |
| Gas Cartridge / Injector | None | <1.0 ppm (1) |
| Sterilizer Inlet / Inbleed Valve | None | <1.0 ppm |
| Door Seal | None | <1.0 ppm |
| Sterilizer Outlet / Chamber Drain | None | <1.0 ppm |
| Venturi System / Filter | None | <1.0 ppm |
| Emission Control Device Inlet | None | <1.0 ppm |
| **Sterilizer #2 - Model 8XL - Modified (SCAQMD Permit F38295)** | | |
| Gas Cartridge / Injector | None | <1.0 ppm |
| Sterilizer Inlet / Inbleed Valve | None | <1.0 ppm |
| Door Seal | None | <1.0 ppm |
| Sterilizer Outlet / Chamber Drain | None | <1.0 ppm |
| Venturi System / Filter | None | <1.0 ppm |
| Emission Control Device Inlet | None | <1.0 ppm |

Notes:
(1) - PPM = parts per million by volume

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## Ethylene Oxide Mass Emissions Data and Calculations

## Abbott Cardiovascular Systems - Temecula, CA - April 7, 2016
## Abator #2 (F832993) - Sterilizer #2 (F83295)

| DeltaP | SqRtDeltaP | Temp (F) | ppm EtO |
|---|---|---|---|
| | Exhaust Phase | | |
| 0.11 | 0.3317 | 322 | 0.01 |
| 0.11 | 0.3317 | 331 | 2.30 |
| 0.11 | 0.3317 | 342 | 0.01 |
| 0.11 | 0.3317 | 409 | 0.01 |
| 0.11 | 0.3317 | 463 | 0.01 |
| 0.11 | 0.3317 | 482 | 0.01 |
| 0.11 | 0.3317 | 475 | 0.01 |
| 0.11 | 0.3317 | 420 | 0.01 |
| 0.11 | 0.3317 | 417 | 0.01 |
| 0.11 | 0.3317 | 409 | 0.01 |
| 0.11 | 0.3317 | 451 | 0.01 |
| 0.11 | 0.3317 | 440 | 0.01 |
| 0.11 | 0.3317 | 436 | 0.01 |
| 0.11 | 0.3317 | 424 | 0.01 |
| 0.11 | 0.3317 | 409 | 0.01 |
| | Aeration Phase | | |
| 0.11 | 0.3317 | 415 | 0.01 |
| 0.11 | 0.3317 | 436 | 0.01 |
| 0.11 | 0.3317 | 421 | 0.01 |
| Average = | | | |
| 0.1100 | 0.3317 | 417 | |
| | = | 877 | degR |

| | | |
|---|---|---|
| **stack ID =** | 3 | in. |
| **stack area =** | 0.049 | sq. in. |
| **press =** | 28.80 | in. Hg |
| **Tstd =** | 528 | deg R |
| **Pstd =** | 29.92 | in Hg |
| **Cp =** | 0.99 | |
| **Kp =** | 85.49 | |
| **Velocity =** | 29.01 | ft/sec |
| **Flow =** | **48.0** | **dscfm** |
| **MWeto =** | 44.05 | |
| **MolVol =** | 385.32 | |
| **ppmv/ft3 =** | 1000000 | |
| **EtO Mass Flow (Exh) =** | **0.00000089** | **lbs/min** |
| **min/cycle =** | 31 | |
| **cycles/year =** | 104 | |
| **EtO Emissions (Exh) =** | **0.0029** | **lbs/year** |
| **EtO Mass Flow (Aer) =** | **0.00000005** | **lbs/min** |
| **min/cycle =** | 6 | |
| **cycles/year =** | 104 | |
| **EtO Emissions (Aer) =** | **0.00003** | **lbs/year** |
| **Total EtO Emissions =** | **0.0029** | **lbs/year** |

Average Exhaust Concentration = **0.1627** **ppm**

Average Aeration Concentration = **0.0100** **ppm**

# ECSi, Inc.

## Ethylene Oxide Mass Emissions Data and Calculations

## Abbott Cardiovascular Systems - Temecula, CA - April 7, 2016
## Abator #1 (F71623) - Sterilizer #1 (F83294)

| DeltaP | SqRtDeltaP | Temp (F) | ppm EtO |
|---|---|---|---|
| | Exhaust Phase | | |
| 0.11 | 0.3317 | 315 | 0.01 |
| 0.11 | 0.3317 | 322 | 0.01 |
| 0.11 | 0.3317 | 327 | 0.01 |
| 0.11 | 0.3317 | 366 | 0.01 |
| 0.11 | 0.3317 | 414 | 0.01 |
| 0.11 | 0.3317 | 458 | 0.01 |
| 0.11 | 0.3317 | 462 | 0.01 |
| 0.11 | 0.3317 | 431 | 0.01 |
| 0.11 | 0.3317 | 417 | 0.01 |
| 0.11 | 0.3317 | 389 | 0.01 |
| 0.11 | 0.3317 | 366 | 0.01 |
| 0.11 | 0.3317 | 392 | 0.01 |
| 0.11 | 0.3317 | 337 | 0.01 |
| 0.11 | 0.3317 | 321 | 0.01 |
| 0.11 | 0.3317 | 315 | 0.01 |
| | Aeration Phase | | |
| 0.11 | 0.3317 | 327 | 0.01 |
| 0.11 | 0.3317 | 322 | 0.01 |
| 0.11 | 0.3317 | 319 | 0.01 |
| Average = | | | |
| 0.1100 | 0.3317 | 367 | |
| | = | 827 | degR |

| | | |
|---|---|---|
| **stack ID =** | 3 | in. |
| **stack area =** | 0.049 | sq. in. |
| **press =** | 28.80 | in. Hg |
| **Tstd =** | 528 | deg R |
| **Pstd =** | 29.92 | in Hg |
| **Cp =** | 0.99 | |
| **Kp =** | 85.49 | |
| **Velocity =** | 28.17 | ft/sec |
| **Flow =** | **49.5** | **dscfm** |
| **MWeto =** | 44.05 | |
| **MolVol =** | 385.32 | |
| **ppmv/ft3 =** | 1000000 | |
| **EtO Mass Flow (Exh) =** | **0.00000006** | **lbs/min** |
| **min/cycle =** | 46 | |
| **cycles/year =** | 104 | |
| **EtO Emissions (Exh) =** | **0.0003** | **lbs/year** |
| **EtO Mass Flow (Aer) =** | **0.00000006** | **lbs/min** |
| **min/cycle =** | 6 | |
| **cycles/year =** | 104 | |
| **EtO Emissions (Aer) =** | **0.00004** | **lbs/year** |
| **Total EtO Emissions =** | **0.0003** | **lbs/year** |

Average Exhaust Concentration = **0.0100** **ppm**

Average Aeration Concentration = **0.0100** **ppm**